

# Progress Report Guidance to Services Research Branch Grantees

(Revised November 2010)

**Every year, NIH grantees are required to submit an application for continued funding of their projects, commonly referred to as a "progress report." Progress reports serve four primary functions:**

- a) They form a public record of your research achievements for any citizen to request, and the basis for continuing the funding of your project**
- b) They may be the primary source of status details used by NIH in responding to inquiries from Congress and others regarding your project. .**
- c) They provide summaries of progress to offices outside NIDA for grants that are supported by "special funding" such as HIV/AIDS, special populations, criminal justice, ARRA, etc.**
- d) Their contents are carefully considered when making decisions about requests for supplements and extensions.**

**The due date for Progress Reports is noted in your eRA Commons account. Note that delays in submitting timely and complete reports are likely to result in delays in subsequent awards.**

**The following information must be included in your progress report regardless of NIH form or format specified. Progress Reports missing this information will be returned for revision. There is always additional narrative space to include this information if not specified on the form.  A gray box highlights a common error or omission in progress reports.**

## **PERSONNEL**

**Other Support:** Use this space to indicate changes in key personnel support varying 25% +/- time from that stipulated in the original application. Changes greater than 25% +/- budget must be approved by the PO in writing before they go into effect. Use this space to summarize previously approved changes since that last report. Upload biosketches (max 4 pages each person) for previously-approved new staff not in the original application as a single .pdf file under "Other File."

**Anticipated Changes:** Use this space to inform the PO of anticipated changes affecting staff level of effort (+/- 25%) that could affect the budget, such as a change in institutional affiliation for key staff, absences of more than 90 days, etc.

**COMMENT: The progress report is NOT where you inform your PO that you have made significant changes to key personnel named in the original application.** Significant variance in percentage of time or level of effort (25% or more), or staff replacements, must be discussed with the PO and approved by the PO in advance of the decision. A biosketch should be submitted to the PO for approval prior to a hiring decision. After hiring, document the change as progress and upload sketches under "Other File."

**Policy:** The request for approval of a substitute PD/PI or senior/key person should include a justification for the change, the biographical sketch of the individual proposed, other sources of support, and any budget changes resulting from the proposed change. If the arrangements proposed by the grantee, including the qualifications of any proposed replacement, are not acceptable to the NIH awarding IC, the grant may be suspended or terminated.

## **BUDGET**

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This is a long-standing NIH requirement repeated here because it is the most common reason progress reports are returned for revision. If the estimated amount of unexpended funds is likely to exceed 25% of that year's budget:

- a) Indicate the percentage and amount in dollars,
- b) Explain the reason for the excess carryover (e.g., IRB delay).
- c) Specify what proactive measures you plan to take to realign your budget to get below the 25% carryover (e.g., hire more field workers to speed recruitment).

Your history of resource management is a significant factor when deciding to extend carry-over requests beyond one year.

### TRAINING

**Human Subjects Education:** Indicate the numbers and roles of staff requiring training and indicate the date on which all staff training will be completed and administratively cleared with NIDA Grants Management.

**Project-Related Training:** Indicate the numbers and roles of staff who need training in how to use the study intervention, measurement/data collection, or protocols.

### DATA COLLECTION

Following the enrollment tables on your form, in the “**Comment for NIH**” narrative space provide details on:

- a) **IRB status:** (Approved or Pending)
- b) **Data and Safety Monitoring Issues:** Summarize all adverse events occurring in the reporting year regardless of whether you previously reported them to NIDA or NIH.
- c) **DSMB Meetings and Minutes:** If a DSMB was promised in the application,
  - a. provide a current roster of DSMB members (note DSMB composition and any changes should have been previously approved by your PO),
  - b. indicate the dates of all meetings during the reporting year,
  - c. summarize DSMB support and decisions, and
  - d. email DSMB meeting minutes to your PO for upload into the grant folder.
- d) **Clinicaltrials.gov Enrollment Status:** (Enrolled, In Process, or Not Applicable & reason).
- e) **Human Subjects:** Describe any changes in human subject protection and the reasons for changes.
- f) **HS Enrollment:\*** Summarize enrollment progress with N and %, commenting on any subgroup deficiencies and proactive measures to meet projected enrollment in the original application;
- g) **HS Follow-up:\*** Summarize follow-up rates with N and %, commenting on any subgroup deficiencies and proactive measures to meet projected enrollment in the original application.

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\* SRB expects 80% follow-up as a bare minimum – 90% is the norm. When your progress with enrollment and follow-up rates fall beyond 80% of target for the reporting period you must a) explain the nature of the problem, and b) what measures you are taking to exceed 80%.

### **RESULTS**

**A. Specific Aims:** Summarize in bulleted/numbered form the aims from the original application – it is not acceptable to merely state: “*The specific aims of the study have not been modified since the initial application.*” Outside officials may not have access to this information.

**B. Studies and Results:**

- a. **Progress:** Provide a narrative summary of progress, including interviews completed, assessments conducted, surveys collected, analyses, data clean-up, coding, etc. Be detailed using numbers and percentages as appropriate. Include figures and tables of work in progress to augment progress communication. Stipulate analyses completed, their purpose, and support/rejection of hypotheses. Make reference to papers and publications. If no scholarly progress, say so.
- b. **Findings:** Overview interim or preliminary results of significance that can help justify the government’s investment in the project.

c. **HIV/AIDS:** If coded HIV/AIDS (i.e., there is an HIV/AIDS aim and hypotheses and/or an HIV/AIDS designation in your Notice of Grant Award), comment on HIV/AIDS-related progress and results separately.

d. **Supplements:** Provide separate progress and results report summaries for each supplement to this grant.

**C. Significance:** If a result stands out, bring it to your PO’s attention here.

**D. Plan:** In a succinct paragraph or two, summarize plans for the next 12 months. Be specific. Use numbers, dates, etc.

**E. Publications:** List separately, by type:

- a. **PUBS:** List all publications acknowledging this grant during the reporting year using the format for the “Upload Science” section. A publication from 2 or 3 years ago is not reflective of current progress. Do not repeat them. Follow the required Public Access Policy instructions for obtaining and reporting PMCID or NIHMSID numbers (<http://publicaccess.NIH.gov>). The appropriate ID number (which depends on journal deposit rules and time elapsed since publication) must be included in your progress report.

*Any publication listed without an NIHMSID or final PMCID will trigger a notice to you and your institution, and may result in other administrative action.*

- b. **IN PRESS:** List all articles in press (re-list in next year’s report as publications).

- c. **IN REVIEW:** List manuscripts in review.

- d. **PAPERS/POSTERS:** List scholarly presentations, and the date and conference at which presented.

**Note:** *list only manuscripts attributed to this grant. While other publications may demonstrate overall productivity, they do not count in Program’s assessment of the current grant’s progress.*